IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

GARY L. BELLER and
MARY K. BELLER, husband and wife,

Plaintiffs,

vs.

COLOPLAST A/S,
COLOPLAST CORPORATION, and
COLOPLAST MANUFACTURING, US LLC,

Defendants.

8:16CV09

ORDER

This matter is before the Court on Plaintiffs' Motion to Compel Defendants' Discovery Answers (Filing No. 83). The Court will grant the motion, in part.

BACKGROUND

Gary and Mary Beller filed this products liability and negligence action against the Coloplast defendants on January 11, 2016. (Filing No. 1). Plaintiffs allege that on January 24, 2014, Gary underwent surgery to implant Coloplast's "Virtue male sling device" to treat his urinary incontinence, and that since the surgery, Gary has experienced scrotum and groin pain, pain while urinating, sexual side effects, and worsening incontinence. (Filing No. 1 at pp. 2-4). Plaintiffs assert that Defendants first started developing the Virtue product in approximately February 2008, and over the next three years, sold over 1,000 devices. Plaintiffs allege Defendants made at least two design changes during that time. (Filing No. 84 at p. 2).

Plaintiffs' Complaint contains seven claims against the defendants for (1) negligence, (2) Strict Liability (Design Defect), (3) Strict Liability (Manufacturing Defect), (4) Strict Liability (Failure to Warn), (5) Breach of Express Warranty, (6) Breach of Implied Warranty, and (7) Loss of Consortium. For their negligence claim, Plaintiffs allege Defendants breached their duty of care in numerous ways, including: failing to conduct sufficient testing and studies to ensure the safety and efficacy of the Virtue; failing to warn Gary or his health care providers of the risk and side effects presented by the Virtue; failing to provide adequate instructions regarding certain

health and safety precautions that Gary and his health care providers would have observed had such instructions been provided; and failing to develop and distribute appropriate procedures for removal of the Virtue by Gary's health care providers. (Filing No. 1).

Plaintiffs served Defendants Coloplast Corp. and Coloplast Manufacturing with a First Set of Interrogatories and First Set of Requests for Production of Documents on May 18, 2016.[1] (Filing No. 85-2 at p. 12). Coloplast Corp. and Coloplast Manufacturing served their answers, objections, and responses on July 18, 2016.[2] (Filing No. 85-4 at p. 18, Filing No. 85-5 at p. 51). Defendants continued to produce documents over the next several months. On January 3, 2017, counsel for Plaintiffs sent a letter to defense counsel outlining Plaintiff's issues with Defendants' answers to interrogatories and method of document production. The parties were unable to resolve their dispute, and Plaintiffs filed a motion to compel on March 15, 2017. (Filing No. 37). Plaintiffs sought substantive answers to Interrogatory Nos. 4, 13, and 19, and requested that Defendants be required to identify how each document they produced was responsive to each Request. (Filing No. 38).

Pursuant to the Defendants' request (and with agreement of Plaintiffs' counsel), Magistrate Judge F.A. Gossett held an informal discovery conference regarding the motion to compel on March 30, 2017. The parties represented to Judge Gossett that the issues raised regarding Interrogatory Nos. 4, 13, and 19 were either moot or resolved. The issue regarding Defendants' identification of responsive documents was not resolved, and Judge Gossett permitted briefing to continue on the motion to compel. (Filing No. 49). Following the conference, the parties reached an agreement on the issue of document production, and the Plaintiffs withdrew their motion to compel on April 13, 2017. (Filing No. 50; Filing No. 52).

With the written discovery issues apparently resolved, the parties continued with scheduling depositions, preparing expert reports, and other discovery. (Filing Nos. 62-65, 68-72). The parties also attended mediation on June 28, 2017, which was unsuccessful, but did not

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[1] At the time Plaintiffs served these discovery requests, it appears that Defendant Coloplast A/S, a foreign corporation with its principal place of business in Denmark, may not have been served with summons in this action. According to the Proof of Service filed by Plaintiffs on July 6, 2016, the Ministry of Justice of Denmark accepted service on behalf of Coloplast A/S on May 31, 2016, nearly two weeks after Plaintiffs served their discovery requests. (Filing No. 26).

[2] Coloplast A/S filed its Answer to the Complaint on July 26, 2016, after the other Coloplast defendants served their discovery responses. (Filing No. 27).

request that the Court stay the case. (Filing No. 66). On October 17, 2017, the Court entered a second amended final progression order extending case progression deadlines, in accordance with the parties' agreed upon motion. (Filing No. 66; Filing No. 67). The amended final progression order set February 5, 2018, as the deadline to complete written discovery, and March 5, 2018, as the deadline to file discovery motions as to matters ripe for decision.[3] (Filing No. 67).

The current dispute concerns the same set of interrogatories and requests for production of documents that Plaintiffs first served on Coloplast Corp. and Coloplast Manufacturing on May 18, 2016.[4] On February 27, 2018, Plaintiffs' counsel sent defense counsel a letter identifying multiple deficiencies with the Defendants' July 18, 2016, answers to interrogatories and responses to requests for production of documents. (Filing No. 85-14). In Plaintiffs' February 27, 2018, letter, they informed Defendants that answers to Interrogatory Nos. 1-4, 7, 9, 12, 13, and 15-16 (mislabeled as 18-19) were deficient, and requested supplemental responses to Request for Production Nos. 10, 16-35, 37-38, 55-57, and 63. Plaintiffs also requested that Coloplast A/S provide answers and responses to the discovery requests within ten days. Plaintiffs demanded Defendants' response to the letter within two business days. (Filing No. 85-14).

The next day, on February 28, 2018, counsel for Plaintiffs contacted the chambers of the undersigned magistrate judge to schedule a telephone conference to resolve the dispute prior to filing a motion to compel, as the March 5, 2018, deadline for filing motions to compel was fast approaching. (Filing No. 73; Filing No. 75). In advance of the conference, on March 2, 2018, Plaintiffs submitted their statement of the discovery dispute to the undersigned magistrate judge by email, identifying additional deficient answers to interrogatories and responses to requests for production of documents to those previously identified in their February 27, 2018, letter to the Defendants: Interrogatory No. 10, and Request for Production Nos. 3, 5, 7, 12, 15, 36, 53, 58, and 61-62. (*Compare* Filing No. 85-14 *with* Filing No. 85-15 at pp. 4-8).

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[3] This court's usual practice is to set the discovery motion deadline before the written discovery deadline (See, e.g., Filing No. 25), but in this case, the parties agreed to extend the discovery motion deadline after the close of written discovery. (Filing No. 66).

[4] As stated above, the Ministry of Denmark accepted service of process on behalf of Coloplast A/S two weeks after Plaintiffs had already served the discovery requests on the other Coloplast defendants. (Filing No. 26).

The Court held the conference on March 5, 2018. Following that conference, the Court ordered defendant Coloplast A/S to provide responses to Plaintiffs' discovery requests and allowed the other defendants to supplement their responses as necessary on or before March 30, 2018. (Filing No. 77).

After certain supplementation by Defendants on March 29, 2018, and email exchanges between the parties, they met and conferred by telephone on April 4, 2018, to discuss the ongoing dispute. (Filing No. 85-1 at p. 6). According to Plaintiffs, during the meet and confer, Plaintiffs requested that Defendants withdraw all objections and supplement answers to Interrogatory Nos. 1-4, 7-9, 12, 13, and 15-16, and to withdraw objections and supplement Request for Production Nos. 2, 5, 7, 9, 10-13, 15-38, 41-45, 47, and 54-64. (Filing No. 85-1 at pp. 6-7, ¶ 36).

Plaintiffs thereafter filed the instant motion to compel on April 9, 2018, requesting that the Court order Defendants to: (1) "verify under oath all of Defendants' answers and supplemental answers to Plaintiffs' Interrogatories;" (2) have Defendant Coloplast A/S serve supplemental answers to Plaintiffs' Interrogatories and Requests for Production in which Coloplast A/S separately repeats and answers each of those discovery requests; (3) withdraw all objections to Plaintiffs' Interrogatory Nos. 1-4, 7, 8, and 12-15 and to provide a supplemental answer to each of those interrogatories, without objection; (4) withdraw all of Defendants' objections to Plaintiffs' Request for Production Nos. 2, 5, 7, 9, 11-13, 16-18, 20-27, 29-38, 41-44, and 57-64 and to provide a supplemental responses to each of those requests, without objection, that fully responds to those requests; (5) disclose to Plaintiffs the search terms, date ranges, custodians, and custodial locations (*e.g.*, hard drives, networks, servers, etc.) that Defendants searched for ESI) that Defendants used to search for ESI; and (6) perform a proper ESI search using search terms, date ranges, and custodial locations upon which Plaintiffs agree. (Filing No. 83).

ANALYSIS

I. Requirements for Filing a Motion to Compel

This court imposes at least two requirements before a party may file a motion to compel: (1) the moving party must first contact the chambers of the assigned magistrate judge to schedule

a conference, and (2) the moving party must engage in "personal consultation" with opposing parties in a sincere attempt to resolve the differences. See Filing No. 67 at p. 2; NECivR 7.1(i). The local rule defines "personal consultation" as "person-to-person conversation, either in person or on the telephone." Letters and emails are only a substitute for personal consultation when the moving party shows that "person-to-person conversation was attempted by the moving party and thwarted by the nonmoving party." NECivR 7.1(i). The informal telephone conference with the assigned magistrate judge is not a substitute for the personal consultation required by NECivR 7.1(i). And, when filing a motion to compel, the motion "must include a certification that the movant has in good faith conferred or attempted to confer with the person or party failing to make disclosure or discovery in an effort to obtain it without court action." Fed. R. Civ. P. 37(a)(1).

In this case, defendants Coloplast Corp. and Coloplast Manufacturing first served their answers to interrogatories and responses to requests for production of documents on July 18, 2016. (Filing No. 85-14). At that time, Plaintiffs identified certain issues with the Defendants' answers, responses, and production of documents, culminating in Plaintiffs filing a motion to compel on March 15, 2017. (Filing No. 37). Plaintiffs ultimately withdrew that motion to compel on April 13, 2017, after reaching an agreement with the Defendants on those issues. (Filing No. 52).

More than ten months passed between the date Plaintiffs withdrew their motion to compel and February 27, 2018, the date Plaintiffs sent a letter to the defendants identifying, for the first time, a litany of issues with the Defendants' July 18, 2016, discovery responses and subsequent document production. At the time Plaintiffs sent this letter, the deadline for parties to complete written discovery had expired, and the deadline for filing motions to compel was less than a week away. (Filing No. 67). Three days after sending their initial letter to Defendants, Plaintiffs identified several more deficient discovery responses in their letter to the Court that Plaintiffs had not identified in their letter to the Defendants. (*Compare* Filing No. 85-14 *with* Filing No. 85-15 at pp. 4-8).

Besides the conference with the court, the only "personal consultation" with defense counsel that Plaintiffs identify took place on April 4, 2018 (and in that meet and confer, Plaintiffs identified additional issues than those they previously had identified in either their February 27, 2018, letter to Defendants, or their letter to the Court). (*Compare* Filing No. 85-1 at pp. 6-7 ¶ 36

with Filing No. 85-14 *and* Filing No. 85-15). The rest of Plaintiffs' communications with Defendants took place by letter or email, only one of which was sent to Defendants prior to the expiration of the motion to compel deadline of March 5, 2018.[5] Before the April 4, 2018, phone call, Plaintiffs offered no showing that they attempted any person-to-person conversation that was thwarted by the Defendants, although they had ample time to do so. See NECivR 7.1(i); see also *Sampson v. Schenck*, No. 8:07CV155, 2010 WL 2737050, at *3 (D. Neb. July 9, 2010)(Thalken, J.)(concluding e-mail correspondence was not "personal consultation" as defined by the local rule "because the plaintiff failed to show that a prior person-to-person conversation occurred or was even attempted by the plaintiff yet thwarted by the defendants."). Failure to show personal consultation as required by NECivR7.1(i) is grounds alone to deny a motion to compel. *Shanghai Foretex Fashion Co. v. Wes & Willy, LLC*, No. 8:14CV106, 2014 WL 12605521, at *2 (D. Neb. July 29, 2014)(Zwart, J.).

Under the circumstances, the Court will consider Plaintiffs' motion to compel only to the extent Plaintiffs raised those issues in their February 27, 2018, letter to the Defendants. The Court will liberally treat the letter as Plaintiffs' "sincere attempt" to obtain the disputed discovery before the motion to compel deadline, even though Plaintiffs called to request a conference with the Court before Defendants could respond. Besides that letter, Plaintiffs offered no evidence of "sincere attempts" through "personal consultation" to obtain the disputed discovery without court action prior to the March 5, 2018, motion to compel deadline, and offered no reason why they could not have raised these issues earlier.[6] See *Heim v. BNSF Ry.*

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[5] Discovery matters arising *after* the March 5, 2018, deadline "may be the subject of motions until the deposition deadline," which in this case was April 9, 2018. (Filing No. 67). However, the discovery issues cited by Plaintiffs pertain to the Defendants' July 2016 discovery responses, and arose long before the March 5, 2018, deadline. To the extent the Court extended the March 5, 2018, motion deadline, such extension only applied to Plaintiffs' right to file a motion to compel on those issues identified by Plaintiffs prior to its expiration.

[6] Other courts have denied technically timely filed motions to compel where the moving party waited unreasonably long to bring the issues before the court. See, e.g., *Austin v. United Parcel Serv. Inc.*, 2002 WL 31050867, at *1 (S.D. Iowa Sept. 13, 2002)(affirming magistrate judge's decision to deny a motion to compel as untimely because although the motion was technically filed on time, the plaintiff had the defendant's discovery responses and objections for nearly five months, during which time the plaintiff did not seek intervention of the court to correct perceived deficient discovery responses); *accord Haviland v. Catholic Health Initiatives-Iowa, Corp.*, 692 F. Supp. 2d 1040, 1044 (S.D. Iowa 2010)(affirming magistrate judge's denial of motions to compel as untimely where plaintiffs waited until eleven days before the discovery deadline to file the motions related to discovery issues that had been identified by the parties for over a year); *Buttler v. Benson*, 193 F.R.D. 664, 666 (D. Colo. 2000)(denying motion to compel where the plaintiff waited one and one-half years after the initial discovery request to file a motion

Co., No. 8:13CV369, 2014 WL 6949044, at *5 (D. Neb. Dec. 8, 2014)(Zwart, J.)(denying motion to compel as to a request for production of documents because "plaintiff has failed to meet his burden of showing he made 'sincere attempts' through 'personal consultation' to obtain the disputed discovery.").

Although Plaintiffs raised issues with additional discovery responses in its letter to the Court dated March 2, 2018, Plaintiffs did not attempt to meet and confer with Defendants regarding those responses prior to bringing them before the Court. To the extent Plaintiffs raised further issues during the parties' April 4, 2018, meet and confer, such issues were ripe for over a year and could have been raised by Plaintiffs in their February 27, 2018, letter, or at any point prior to the motion to compel deadline of March 5, 2018. Plaintiffs offered no reason for the Court to extend the scheduling order deadline to accommodate Plaintiffs' late attempt to procure substantial supplementation of Defendants' discovery responses more than ten months after withdrawing their first motion to compel regarding the same discovery responses.

The Court's limitation of Plaintiffs' motion is appropriate considering that written discovery had been closed since February 5, 2018; Plaintiffs knew what the court requires before a party may file a motion to compel; Plaintiffs knew the motion to compel deadline was March 5, 2018, but waited until February 27, 2018, to first raise multiple new issues with the Defendants' July 2016 discovery responses; Plaintiffs already filed a motion to compel regarding the same discovery responses in March 2017; and the prejudice to Defendants by permitting a wholesale reopening of disputes concerning discovery responses that Defendants reasonably believed the parties had resolved in April 2017. See *Klein v. TD Ameritrade Holding Corp.*, No. 8:14CV396, 2017 WL1316944, at *2 (D. Neb. Apr. 7, 2017)(citing *Bialas v. Greyhound Lines, Inc.*, 59 F.3d 759, 764 (8th Cir. 1995))("A magistrate judge is afforded broad discretion in the resolution of nondispositive discovery disputes."); *Desert Orchid Partners, L.L.C. v. Transaction Sys. Architects, Inc.*, 237 F.R.D. 215, 218 (D. Neb. 2006)(citing *Pavlik v. Cargill, Inc.*, 9 F.3d 710, 714 (8th Cir. 1993))("District courts have broad discretion to limit discovery and decide discovery motions.").

Accordingly, the Court will only consider Plaintiffs' motion to compel to the extent Plaintiffs presented those issues to Defendants in their February 27, 2018, letter. This includes

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to compel, concluding that "the plaintiff ha[d] failed to seek judicial relief for an unreasonably long period of time.").

Plaintiffs' request that Defendants supplement their answers to Interrogatory Nos. 1-4, 7, 12, 13, and 15, and to supplement responses to Request for Production of Document Nos. 16-18, 20-27, 29-35, 37-38, 57, and 63. (*Compare* Filing No. 85-14 *with* Filing No. 83). The Court will also consider the issue of Coloplast A/S's answers and responses that adopted the objections and answers of Coloplast Corp. and Coloplast Manufacturing. Finally, the Court will consider any agreements or stipulations that Defendants have made with Plaintiffs regarding supplementation of outstanding discovery responses. The remainder of Plaintiffs' motion is denied for the reasons discussed above.

II. Coloplast A/S's Discovery Responses

Following the telephone conference with the parties on March 5, 2018, the Court ordered Coloplast A/S to provide responses to Plaintiffs' discovery requests. During the telephone conference, defense counsel indicated this supplementation may be in the form of adopting the answers and responses of Coloplast Corp. and Coloplast Manufacturing, which is what Coloplast A/S ultimately did.[7] (Filing No. 85-7; Filing No. 87-8). Plaintiffs now seek an order compelling Coloplast A/S to serve supplemental answers and responses that separately repeat and answer each and every discovery request.

The issue with Coloplast A/S's responses to discovery is not straightforward. At the time Plaintiffs served Coloplast Corp. and Coloplast Manufacturing with the First Set of Interrogatories and First Set of Requests for Production of Documents on May 18, 2016, Coloplast A/S, a foreign corporation with its principal place of business in Denmark, appears to not yet have been served with process, and had not yet filed a responsive pleading to the complaint.[8] According to Plaintiffs' proof of service of process filed on July 6, 2016, the Ministry of Justice of Denmark accepted service on behalf of Coloplast A/S on May 31, 2016, two weeks after Plaintiffs served their discovery requests. (Filing No. 26). Coloplast A/S

[7] According to the corporate disclosures filed in this case, Coloplast A/S a parent/grand-parent company of Coloplast Corp. and Coloplast Manufacturing (Filing No 15; Filing No. 16). The Coloplast defendants are represented by the same counsel.

[8] The Court is not conclusively determining when Coloplast A/S was actually served with process. Coloplast Manufacturing and Coloplast Corp. had raised the service of process issue in the Rule 26(f) Report filed on March 28, 2016, noting that "putative Defendant Coloplast A/S, which has not been served, is a foreign corporation that on information and belief is not subject to the jurisdiction of this Court and is not a proper defendant in this case." (Filing No. 19).

thereafter filed its answer to the complaint on July 26, 2016, after the other Coloplast defendants had already responded to Plaintiffs' discovery requests. And when Coloplast Corp. and Coloplast Manufacturing served their responses to discovery on July 18, 2016, they objected to Plaintiffs' interrogatories and requests to the extent that they sought information from Coloplast A/S, and stated that Coloplast Corp. and Coloplast Manufacturing were the only two respondents to the discovery requests. (Filing No. 85-4 at p. 1; Filing No. 85-5 at p. 1). It is not clear to the Court if Plaintiffs re-served Coloplast A/S with the discovery requests after Coloplast A/S filed its answer to the complaint, and thus it is equally unclear at what point, if any, Coloplast A/S was required to respond to those requests. Additionally, Coloplast A/S's non-response to Plaintiffs' discovery requests would have been apparent to Plaintiffs at the time they filed their first motion to compel in March 2017.

Under the circumstances, the Court will deny Plaintiffs' request for Coloplast A/S to serve supplemental answers and responses that separately repeat and answer each and every discovery request, which at this stage of the proceedings would serve no real purpose. Coloplast A/S's adoption of the other Coloplast defendants' answers and responses is sufficient.

Plaintiffs further request that the Court compel Defendants to verify under oath all answers and supplemental answers to Interrogatories as required by Fed. R. Civ. P. 33(b). Defendants represent they served supplemental answers on April 20, 2018, with signed verification, and the Court agrees that it serves no purpose to order Coloplast to verify the originally served interrogatory answers, so long as the supplemental answers contained the signed verification. (Filing No. 89 at p. 7). Accordingly, this request of the Plaintiffs is denied.

III. Substantive Rulings

Federal Rule of Civil Procedure 33 provides, "An interrogatory may relate to any matter that may be inquired into under Rule 26(b)." Fed. R. Civ. P. 33(a)(2). "Each interrogatory must, to the extent it is not objected to, be answered separately and fully in writing under oath." Fed. R. Civ. P. 33(b)(3).

Plaintiffs' motion requests an order compelling Defendants to supplement eleven of their interrogatory answers (eight of which were raised in their February 27, 2018, letter) and forty-eight requests for production of documents (twenty-two of which were raised in their February 27, 2018, letter). (*Compare* Filing No. 85-14 *with* Filing No. 83).

A. Interrogatories

After review of Defendants' supplemental answers (Filing No. 90-7) and the parties' briefs, the court makes the following rulings regarding Plaintiffs' motion to compel supplemental answers to interrogatories:

> **INTERROGATORY NO. 1**: Identify the specific provision(s) of each governmental or industry regulation, standard, guideline, recommendation, standard practice, or custom that You contend was applicable to the design, manufacture, performance, testing, certification, or safety of the Virtue Device at issue at the time the Product left the Defendants' control.
>
> Defendants objected to this interrogatory then answered:
>
> Subject to the foregoing objections, Coloplast responds that the Virtue Device is a Class II device regulated in the United States by the Food and Drug Administration (FDA). The Virtue's regulatory history has been produced to the Plaintiffs. The Virtue received initial clearance by FDA on October 17, 2008. Coloplast submitted three Special 510(k) applications that the FDA cleared on May 7, 2009; June 3, 2010; and August 17, 2011 respectively. A traditional 510(k) for changes to the Virtue—including a "dimensional decrease of the central mesh body at its narrow portion and other minor dimensional changes" and the "addition of knots near the distal end of each suture"—received pre-market clearance on February 14, 2012. The Virtue Device is subject to the applicable regulations and standards related to Class II devices. Regulations that may apply outside the Unites States are not relevant to this suit.
> Coloplast further supplements its response by stating that Virtue is subject to standards, including but not limited to the following:
> ☐ISO 10993-1 and many standards related thereto
> ☐ISO 14971
> ☐MEDDEV 2.7.1 (December 2009) Evaluation of Clinical Data: A Guide for Manufacturers and Modified Bodies
> ☐Medical Device Directive 93/42/ECC as amended by Directive 2007/47/EC
> ☐Regulations promulgated by Health Canada
> ☐CE marked by DGM (Notified Body No. 04523)
> ☐21 CFR, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies
> ☐FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh
> ☐AST M F2148
> ☐U.S. Pharmacopeia

Court ruling: Defendants have adequately answered the interrogatory by providing Plaintiffs with the regulations they contend were applicable to the Virtue Device, and will not be compelled to supplement this answer further.

> **INTERROGATORY NO. 2**: Identify each component part comprising a Virtue Device, including the manufacturer of each component part and where such manufacture occurs.
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> Defendants answered subject to objections:
>
> Coloplast responds that the Virtue Device comprises surgical mesh, an Alexis retractor, a sleeve, introducers, dispensing tip, and sutures. Coloplast receives these materials and assembles the product. Applied Medical in Rancho Santa Margarita, California, supplies the Alexis retractor. Secant Medical, LLC in Perkasie, Pennsylvania supplies the surgical mesh. Diversified Plastics Inc., in Brooklyn Park, MN, supplies the introducers. Nordson EFD, in East Providence, RI, supplies the Dispensing Tip. Teleflex Inc. in Coventry, CT, supplies the sutures.

In Defendants' brief, they agreed to "investigate whether internal records indicate the location of the manufacture of Virtue's component parts at the time of manufacture of Mr. Beller's implant." (Filing No. 89). Plaintiffs agreed in their Reply brief to narrow this interrogatory to only seek (a) the name and address of each person or entity who manufactured any of the component parts that comprised the particular Virtue product that was implanted in Mr. Beller and (b) the address location of where each such component part was manufactured. (Filing No. 93 at p. 13).

Court ruling: Defendants shall supplement their answer to this interrogatory in accordance with Plaintiffs' narrowed scope as set forth in their Reply brief.

> **INTERROGATORY NO. 3**: Identify all warnings, information or notifications, if any, provided to Plaintiff Gary Beller and his health care providers concerning any defects or Complications of Virtue Devices. Produce copies of any and all such warnings, information and notifications that relate to any of your responses.

Defendants partially supplemented their answer after the April meet and confer. However, Defendants maintain their objection that the interrogatory is not limited to Dr. Feloney (Mr. Beller's implanting physician) and instead demands a response for all of Mr. Beller's "healthcare providers," of which there are at least thirteen. Because Dr. Feloney was the only healthcare provider who participated in the decision to use Virtue and the only

physician involved in the implantation surgery, Defendants assert they limited their answer accordingly:

> Coloplast responds that it supplied Instructions For Use ["IFU"] with the product at issue, produced to Plaintiffs at Bates No. CP Beller90014466. By way of further response, a post-procedure instruction sheet and patient brochures are also routinely provided to physicians and may be, at the physicians' discretion, transmitted to patients. Coloplast supplements its response by stating that Mr. Beller testified in deposition that he had not seen any materials from Coloplast about slings. [Beller Dep. Tr. 200: 12-24]. Coloplast further supplements its response by stating that Dr. Feloney testified in deposition that he typically reviewed package inserts and had no problems with the Virtue package insert. [Feloney Dep. Tr. 79:9-24].

Plaintiffs respond that several doctors besides Dr. Feloney saw Mr. Beller after the Virtue was implanted, and that because Defendants argue the Virtue should be removed from Mr. Beller, Plaintiffs are entitled to know what information, if any, Coloplast has provided to Mr. Beller's healthcare providers besides Dr. Feloney, including any information regarding removal. (Filing No. 93 at p. 14).

Court ruling: Defendants shall supplement this answer to state what, if any, warnings or information were provided to Mr. Beller's healthcare providers beyond Dr. Feloney. To the extent that this interrogatory demands Defendants to produce copies of those documents, such request is improper. See Federal Practice Series, Discovery Proceedings in Federal Court, *Form*, § 14:7 (3d ed.)("[R]equests for production of documents or requests for admissions are inappropriate when contained within interrogatories. In particular, requests for documents to be attached to answers are improper"); *Hickman v. Taylor*, 329 U.S. 495, 504 (1947)("Rule 33 does not make provision for such production, even when sought in connection with permissible interrogatories.). If Defendants choose to supplement their answer by referring to documents already produced (or by producing additional records), Defendants shall identify those documents by Bates number. See Fed. R. Civ. P. 33(d).

> **INTERROGATORY NO. 4**: Identify all instructions, manuals, and other guidance, if any, provided to Plaintiff Gary Beller's health care providers concerning the recommended procedure for implantation and removal of Virtue Devices. Produce copies of any and all such instructions that relate to any of your responses.

Defendants supplemented their answer after the meet and confer, subject to objections:

> Coloplast responds that it supplied Instructions For Use with the product at issue, produced to Plaintiffs at Bates No. CP Beller90014466. By way of further response, a post-procedure instruction sheet and patient brochures are also routinely provided to physicians and may be, at the physicians' discretion, transmitted to patients. Coloplast further supplements its response by stating that Dr. Feloney testified in deposition that he typically reviewed package inserts and had no problems with the Virtue package insert. [Feloney Dep. Tr. 79:9-24].

Plaintiffs argue that this supplemental answer is insufficient because Defendants answered over objections. Plaintiffs primarily take issue with Defendants' failure to identify by Bates number the "post-procedure instruction sheet and patient brochures" documents referenced in their answer. (Filing No. 93).

Court Ruling: Defendants' answer is sufficient. Defendants did not choose to answer this question by producing business records in accordance with Fed. R. Civ. P. 33(d), and therefore they are not required to identify documents by Bates number. Plaintiffs asked Defendants to identify instructions, manuals, and guidance provided to Mr. Beller's health care providers, and Defendants have answered the question asked. Additionally, similar to Interrogatory No. 4, to the extent that this interrogatory demands Defendants to produce copies of those documents, such request is improper.

> **INTERROGATORY NO. 7**: If you have ever acquired any information providing evidence of a reasonable association between Virtue Devices and any Complications whatsoever, identify when you received such information, the general content of such information, and any documents reflecting the nature of such information.

Plaintiffs defined "Complication" as "any injury or disorder occurring in a patient caused by or potentially caused by the Virtue device including, but not limited to: bleeding, pain, discomfort, impaired sexual relations, infection, incontinence, inflammation, and any other disease or disorder of the pelvic region." (Filing No. 90-8 at p. 2). Plaintiffs did not define "reasonable association."

Defendants answered that they "identified complications associated with the Virtue device in its IFU, produced to Plaintiffs at Bates No. CP Beller90014466." Defendants objected to further answering "on proportionality grounds," stating:

> Coloplast has provided Plaintiffs with all of the reports of complications associated with Virtue it has received. (Produced as CPBeller800000101-1005). Coloplast cannot provide a sworn statement based on its inference of what Plaintiffs mean by "any information providing evidence of a reasonable association between Virtue Devices and any complications whatsoever." . . . This request is a facially unreasonable fishing expedition explicitly untethered from the facts at issue in this case. Plaintiffs have already received the relevant information to the actual issues of the case. The identified IFU lists the known complications associated with Virtue, and Coloplast has provided comprehensive documentation of all reported complications. Further supplementation by Coloplast would serve no purpose.

Defendants argue that IFU lists the known complications associated with Virtue, and that Defendants have "provided comprehensive documentation of all reported complications." (Filing No. 89 at p. 15). Plaintiffs respond that Defendants must specifically identify by Bates number each of the 900 pages of complications cited by Defendants in answering this interrogatory. (Filing No. 93 at p. 15).

Court ruling: Plaintiffs' interrogatory, while arguably overbroad, also requests relevant information (including when Defendants learned of certain complications associated with the Virtue), and Defendants have chosen to answer this interrogatory by producing "all of the reports of complications associated with Virtue it has received" as set forth in documents CPBeller800000101-1005. "If the answer to an interrogatory may be determined by examining, auditing, compiling, abstracting, or summarizing a party's business records, . . . the responding party may answer by . . . specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could[.]" Fed. R. Civ. P. 33(d). Defendants' general reference to over 900 pages of reports of complications does not comply with Fed. R. Civ. P. 33(d) and is not responsive to the interrogatory. Defendants shall supplement this answer to identify "in sufficient detail" the records so that Plaintiffs may readily locate and identify them.

> **INTERROGATORY NO. 12**: If You met or conferred with any Person or entity, other than Defendants' employees, to discuss whether there was an

> association or causal relationship between Virtue Devices and any Complications, please:
> a. Identify the dates and attendees of each such meeting or communication; and
> b. Produce all documents relating to the meeting or communication.
>
> Defendants objected as follows:
>
> Coloplast objects to this Interrogatory because it is vague, and because it seeks information that is not relevant to any claim or defense in this suit. Coloplast objects to the defined term "You" as overbroad. Coloplast objects that this Interrogatory is unlimited in time with no attempt to focus or limit to the claims at issue in this litigation. Coloplast further objects because responding to this Interrogatory, as made, would cause unreasonable annoyance, oppression, burden, and/or expense to Coloplast, and would require the making of an unreasonable investigation that is not proportional to the needs of the case as set forth in Federal Rule of Civil Procedure 26(b)(l). Coloplast objects to this Interrogatory on the grounds that it seeks information and/or documents protected by the attorney-client privilege and work product doctrine. Coloplast objects on the grounds that it is impossible to respond to the Interrogatory as written and invites Plaintiffs to appropriately narrow this Interrogatory.

Court ruling: Defendants did not address their objections to this interrogatory in their brief in response to Plaintiffs' motion. Defendants shall be required to answer this interrogatory, as clarified by Plaintiffs in their brief: "This interrogatory only asks Defendants to identify the dates when they met with anyone outside of their company to discuss those complications; identify who attended those meetings; and to produce all documents concerning those meetings." (Filing No. 84 at p. 19). However, because Plaintiffs' interrogatory is unlimited in timeframe, the Court will limit the dates of the interrogatory to February 2008 (the date Plaintiffs identify that the Virtue began being developed) and January 24, 2014 (the date of Mr. Beller's surgical implant procedure). Identification of persons and the dates communications took place are unlikely to contain information protected by the attorney-client privilege (which protects communications itself) or protected work-product (which protects mental impressions, opinions, legal theories, and tangible things prepared in anticipation for litigation). Plaintiffs' request for document production contained within this interrogatory is an inappropriate use of an interrogatory and Defendants are not required to produce any documents in supplementing their answer unless they choose to answer by producing business records in accordance with Rule 33(d).

INTERROGATORY NO. 13: If You are aware of any defects of any kind concerning Virtue Devices, including but not limited to any departure from design or manufacturing specifications or any reported instances of a Virtue Device failing to function properly for its intended purpose, please identify:
a. The nature and extent of the defect;
b. The date You first became aware of the defect and how you were made aware (i.e. study, trial, patient complaint);
c. The dates of the disclosure to the FDA or other Agencies, if any; and
d. Attach any and all documents relating to any of Your responses to this interrogatory

Defendants objected as follows:

Coloplast objects to this Interrogatory because it is vague, and because it seeks information that is not relevant to any claim or defense in this suit. Coloplast objects to the defined term "You" as overbroad. Coloplast objects to this Interrogatory on the grounds it assumes such defects exist. Coloplast further objects because responding to this Interrogatory, as made, would cause unreasonable annoyance, oppression, burden, and/or expense to Coloplast, and would require the making of an unreasonable investigation that is not proportional to the needs of the case as set forth in Federal Rule of Civil Procedure 26(b)(l). Coloplast objects on the grounds that it is impossible to respond to the Interrogatory as written and invites Plaintiffs to appropriately narrow this Interrogatory.

Court ruling: Like Interrogatory No. 12 above, Coloplast did address their objections to this interrogatory in their brief in response to Plaintiffs' motion, and therefore the Court finds that that Defendants shall supplement their answer. Plaintiffs' request is directed at obtaining relevant information, and although such request may require a reasonable investigation, the Court cannot say that it this interrogatory is so facially overbroad or burdensome as to sustain Defendants' objections. However, Plaintiffs' request for document production contained within this interrogatory is an inappropriate use of an interrogatory and Defendants are not required to produce any documents in supplementing their answer, unless they choose to answer pursuant to Rule 33(d).

INTERROGATORY NO. 14: Asks for dates and details of "any federal or state governmental or industry investigation of the safety and/or efficacy of Virtue Devices or their component parts[.]" Although Plaintiffs did not mention this interrogatory in their February 27, 2018, letter to Defendants, Defendants stated they will remove their objections to this

interrogatory because they have already responded that the "Virtue Device has never been part of any federal or state governmental or industry investigation into its safety and efficacy." (Filing No. 89 at p. 21). Accordingly, Defendants shall serve a supplemental answer without objections.

> **INTERROGATORY NO. 15**: Please state whether any of your Virtue Devices are not suitable for any particular patient populations. For each such patient population, please state:
> a. The specific patient population for which Your Virtue Device is not suitable, and the reasons why these products are not suitable for the particular patient population;
> b. When You became aware that such patient population was not an appropriate candidate for your Virtue Device(s); and
> c. The date and manner in which You conveyed this information to physicians and/or patients.

Defendants answered over objections that the interrogatory is vague, seeks irrelevant information, is overbroad and unduly burdensome, and is not proportional to the needs of the case:

> Coloplast refers Plaintiffs to the contraindications identified in Virtue's Instructions For Use, produced to Plaintiffs at Bates No. CP Beller90014466. Virtue is an implantable medical device indicated for treatment of male stress urinary incontinence. Virtue is available by prescription only and used under the direction of a physician, including appropriate patient selection.

Defendants argue that, because Virtue is a prescription medical device sold to physicians and hospitals, "it is the physician's responsibility to select appropriate patients for treatment with the device." Defendants further argue that their answer identifying the IFU by Bates number is a sufficient answer because the IFU contains the information necessary to assist physicians in patient selection, including contraindications and warning. Defendants additionally assert that "[t]here are four contraindications, none of them relevant to the case." (Filing No. 89 at p. 14).

Court Ruling: Defendants shall supplement their answer to fully respond to this interrogatory, which seeks relevant information. In developing, manufacturing, and marketing the Virtue, Defendants would have learned what, if any, type of patient population the Virtue is unsuitable for, which is relevant to Plaintiffs' claims. In particular, one of the issues in this case is whether Mr. Beller's prior Prostate Brachytherapy treatment caused pre-existing conditions making him an inappropriate candidate for the Virtue sling (which Plaintiffs assert their experts

have opined to be the case. See Filing No. 93 at p. 18). Whether Defendants knew that a patient such as Mr. Beller would not be a suitable candidate for the Virtue may be relevant to Plaintiffs claims, including the claim for failure to warn.

In sum, Defendants shall serve supplement answers to Interrogatory Nos. 2, 3, 7, 12, and 13-15, as set forth above.

B. Requests for Production of Documents

Federal Rule of Civil Procedure 34 permits a party to serve another party with requests to produce documents within the scope of Fed. R. Civ. P. 26(b). Fed. R. Civ. P. 34(a). Requests must be made "with reasonable particularity" and "may specify the form or forms in which electronically stored information is to be produced." Fed. R. Civ. P. 34(b). "For each item or category, the response must either state that inspection and related activities will be permitted as requested or state with specificity the grounds for objecting to the request, including the reasons." Fed. R. Civ. P. 34(b)(2)(B). "An objection must state whether any responsive materials are being withheld on the basis of that objection. An objection to part of a request must specify the part and permit inspection of the rest." Fed. R. Civ. P. 34(b)(2)(C). "A party must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request." Fed. R. Civ. P. 34(b)(2)(E)(i).

The party resisting a motion to compel "has the burden of showing its objections are valid by providing specific explanations or factual support as to how each discovery request is improper" and also "has the burden to show facts justifying its objection by demonstrating that the time or expense involved in responding to requested discovery is unduly burdensome." *Online Res. Corp. v. Joao Bock Transaction Sys., LLC*, No. 8:13CV231, 2014 WL 5173118, at *4 (D. Neb. Oct. 14, 2014)(Thalken, J.)(citing *St. Paul Reinsurance Co., Ltd. v. Commercial Fin. Corp.*, 198 F.R.D. 508, 511-12 (N.D. Iowa 2000); *Wagner v. Dryvit Sys.*, Inc., 208 F.R.D. 606, 610 (D. Neb. 2001)). "This imposes an obligation to provide sufficient detail and explanation about the nature of the burden in terms of time, money, and procedure required to produce the requested discovery." *Wagner*, 208 F.R.D. at 610. "All parties are entitled reasonable access to 'all evidence bearing on the controversy between them, including that in control of adverse parties. This, of course, requires the absolute honesty of each party in answering discovery

requests and complying with discovery orders.'" *Id.* at 609 (quoting *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 91 F.R.D. 574, 576 (S.D. N.Y. 1981)).

The manner in which written discovery has proceeded in this case is troubling. In reading the parties' briefs, it is clear that both parties were, and continue to be, on different pages regarding the scope and manner of production of documents, particularly electronically stored documents, despite their electronic discovery provision conference at the outset of this case. See Filing No. 19 at pp. 17-18 - Rule 26(f) Report). Defendants assert they had previously reached an agreement with Plaintiffs to conduct "targeted" document production; Plaintiffs assert that claim is false. (Filing No. 93 at p. 4). Although Plaintiffs suggest some level of bad faith on Defendants' part, the Court does not find the situation to be anything more than a misunderstanding. Given the disparities in the parties' understanding of the scope of discovery, however, the Court will grant Plaintiffs' request that Defendants disclose the search terms, date ranges, custodians, and custodial locations (e.g., hard drives, networks, servers, etc.) that Defendants used to search for ESI. After such disclosure, the parties are to meet and confer to discuss what, if any, additional search terms, ranges, and custodial locations may be appropriate to perform an additional ESI search. The Court is persuaded that the date ranges of relevant discovery is between February 2008 (the date the Virtue began being developed and designed) and January 24, 2014, the date of Mr. Beller's surgical implant procedure.

The foregoing ESI discovery conference may resolve some of Plaintiffs' issues with Defendants' document production responses; however, the Court will further address Plaintiffs' specific requests for supplemental document production below:

REQUEST NO. 2: Although Plaintiffs did not cite this request as deficient in its February 27, 2018, letter to Defendants, Plaintiffs agreed to narrow this request (Filing No. 84 at p. 26), and Defendants agreed in their brief to "locate and produce available organizational charts for Defendants' North American urology care division/department sufficient for the period of 2008 through 2016." Accordingly, if they have not already done so, Defendants shall comply with this agreement and supplement its production in response to Plaintiffs' narrowed request.

> **REQUEST NO. 16**: Any Documents that identify or list (including in summary format) any completed, proposed, planned, considered, or conceived preclinical

studies as well as clinical trials that assess, evaluate or discuss the safety and/or efficacy or lack thereof of the Virtue Device.

Defendants objected that this request is "vague, ambiguous, and overly broad, is unlimited in scope in terms of time or geographic region, and because the Request seeks information outside of Coloplast's possession, custody, or control." Defendants further objected that the request did not seek relevant information and was unreasonably burdensome and not proportional to the needs to the case. (Filing No. 85-5 at pp. 14-15). Defendants then referred Plaintiffs to its documents produce in response to Request No. 15, which asked for "All Preclinical and Clinical Study reports relating to the Virtue Device."

Plaintiffs argue that Defendants' reference to Request No. 15 is inadequate because that request asked for completed preclinical and clinical studies, whereas this request seeks proposed or considered studies that were never actually performed. Plaintiffs argue this request seeks relevant information because "Documents identifying the proposed, planned, considered, or conceived pre-clinical and clinical trials are relevant to showing which studies Defendants should have been performing, or failed to perform, on the Virtue product before they released it out into the market." (Filing No. 93 at p. 22).

Court Ruling: Defendants shall produce all documents responsive to this request following the parties' ESI conference. Plaintiffs have met their threshold showing of relevance and Defendants have not offered evidence or any support showing that responding to this request would cause an undue burden.

REQUEST NO. 17: All Documents that reflect Defendants' written procedures for the collection, evaluation or dissemination of adverse event reports concerning the Virtue Device.

Defendants respond that they have "produced a master list of complaints" and "individual complaint data." Defendants agree "to produce the policies and procedures regarding adverse event reporting for the time period the Virtue was cleared until the date of Mr. Beller's implant," which would include October 2008 through January 24, 2014. (Filing No. 89 at p. 21).

Plaintiffs assert Defendants' offer is "not enough" because Defendants' proposed time frame is too narrow. Plaintiffs argue that Defendants began working with consultants on the Virtue in fall of 2007, and thus Defendant's offer excludes the "crucial time period when Defendants were developing the Virtue product." (Filing No. 93 at p. 23).

Court Ruling: Defendants shall produce policies and procedures regarding adverse event reporting from February 2008 through January 24, 2014, to the extent they have not already done so.

> **REQUEST NO. 18**: Any electronic database, electronic spreadsheet, or other electronic program in Your possession, custody, or control concerning or comprising adverse event reports generated concerning the use of the Virtue Device.

Defendants assert that they have produced the "complete adverse event reports for the product" and therefore Plaintiffs have the data requested by this request. Defendants contend that production of the underlying databases is unduly burdensome. (Filing No. 89 at p. 20). Plaintiffs argue that Defendants did not meet their burden to substantiate objections to producing the underlying databases for adverse event reports. (Filing No. 93 at pp. 23-24).

Court Ruling: Defendants shall not be compelled to produce entire underlying databases for adverse event reports. "A party resisting facially overbroad or unduly burdensome discovery need not provide specific, detailed support" to raise and stand on its objections." *Madden v. Antonov*, 2014 WL 4295288, 3 (D. Neb. 2014). Additionally, per Rule 26(b)(2)(C), the Court can on its own initiative limit discovery if "the discovery sought is unreasonably cumulative or duplicative;" is "obtainable from some other source that is more convenient, less burdensome, or less expensive;" or "the burden or expense of the proposed discovery outweighs the likely benefit." Fed. R. Civ. P. 26(b)(2)(C)(i)-(iii). Plaintiffs have all adverse event reports, and their request for production for the entire underlying database of adverse reports is not proportional to the needs of this case.

> **REQUEST NO. 20**: All Documents relating to the design of the Virtue Device, including but not limited to Design Validation Protocols and Patent Applications.

Defendants contend this request is facially overbroad and unreasonable. Defendants represent they "produced comprehensive design documents concerning all versions of Virtue in August of 2016" and Plaintiffs' counsel complained the document production was "overwhelming." (Filing No. 89 at p. 17).

Plaintiffs counter that they did not take issue with the quantity of documents, but instead complained about the manner in which Defendants produced the documents. Plaintiffs argue

that this request "goes to the very heart of this lawsuit" and that they need "all documents concerning the design of the Virtue product," including all emails regarding its design, between 2007 and 2015. (Filing No. 93 at pp. 25-26). Plaintiffs assert that emails are significant because from 2008 through 2010, the Virtue device underwent at least two design changes after its initial creation. (Filing No. 84 at p. 48).

Court Ruling: Plaintiffs' request is facially overbroad as framed and not proportional to the needs of the case. Plaintiffs have two claims related to the Virtue's design: a negligence claim and a strict liability (design defect) claim. With respect to their negligence claim, Plaintiffs allege that Defendants breached a duty of care by (1) failing to conduct sufficient testing and studies to ensure the safety and efficacy of the Virtue; (2) failing to warn Plaintiff or his health care providers of the risk and side effects presented by the Virtue; (3) failing to provide adequate instructions regarding certain health and safety precautions that Plaintiff and his health care providers would have observed had such instructions been provided; and (4) failing to develop and distribute appropriate procedures for removal of the Virtue by Plaintiff's health care providers. (Filing No. 19 at p. 3). For their strict liability (design defect) claim, Plaintiffs assert that "At the time the Virtue device left the Defendants' possession, it was defective with respect to its design because it failed to perform safely as expected by an ordinary consumer when used for its intended purpose of treating male urinary incontinence" and that "Defendant failed to develop and issue guidelines for removal of the device as designed." (Filing No. 19 at p. 4). Plaintiffs have not made a threshold showing of relevance to their claims in this case that would necessitate Defendants to search for and produce every single email related to the design of the Virtue from 2007 through 2015, and such request is not proportional to the needs of this case. Defendants represent they have produced comprehensive design documents concerning all versions of the Virtue, which is the information relevant for Plaintiffs to prove that the Virtue, as designed, failed to perform safely as expected by an ordinary consumer.

The parties group Request No. 21, 31, and 63 together as they each deal with any Standard Operating Procedures ("SOP"). These requests ask for:

> **REQUEST NO. 21**: All Documents in Your possession, custody, or control relating to any Standard Operating Procedure ("SOP") and policy and procedure

manuals relating to the manufacture of the Virtue Device during the Relevant Time Period.[9]

REQUEST NO. 31: All Documents in Your possession, custody, or control relating to any SOP and policy and procedure manuals relating to Your post-marketing surveillance for the Virtue Device during the Relevant Time Period.

REQUEST NO. 63: All Documents in Your possession, custody, or control relating to any SOP and policy and procedure manuals relating to the content and format of package inserts, patient information sheets, and other information pertaining to or concerning the Virtue Device during the Relevant Time Period.

Defendants argue that these requests are overbroad and not relevant to the issues in this case because Plaintiffs have raised a single *pro forma* allegation of manufacturing defect. Plaintiffs assert in their brief that they "are only asking for Defendants to produce their policies and procedures" in effect between 2008 through 2016 and are not "asking for any documents whatsoever that may be related to the policies and procedures or any drafts of the policies and procedures." (Filing No. 93 at p. 26; Filing No. 84 at p. 46).

Court Ruling: Defendants shall search for and produce documents responsive to Plaintiffs' requests as narrowed in their briefs.

The parties group Request Nos. 22-26 together, which ask for:

REQUEST NO. 22: All Documents in Your possession, custody, or control reflecting patient complaints of Complications pertaining to the Virtue Device.

REQUEST NO. 23: All Documents in Your possession, custody, or control reflecting physician or health care provider complaints or concerns pertaining to the Virtue Device.

REQUEST NO. 24: All internal communications regarding adverse events, malfunctions, and/or Complications related to the Virtue Device.

REQUEST NO. 25: All Documents received by Defendants that report an adverse event to Defendants, regardless of the source of such Documents, in the original form received by Defendants, excluding any pleadings that initiated litigation against defendants for personal injuries resulting from the use of the Virtue Device.

REQUEST NO. 26: All correspondence and/or other communication prepared and/or sent in response to communication received from doctors, hospitals, healthcare providers, and/or the Virtue Device patients regarding complaints with the Virtue Device and/or adverse events with the Virtue Device, including any and all internal communications.

Defendants argue that they have produced "the substantive information" demanded by Plaintiffs "in the master complaint list and complaint notes" and that they have produced "the

[9] Plaintiffs had defined "Relevant Time Period" as January 1, 2000 to the present. (Filing No. 85-3 at p. 6).

Company's email correspondence related to Mr. Beller." Defendants object to further production because "Many of these records contain personal health information of patients who have no relationship to this case" and would "expose non-parties to the risk of inadvertent disclosure of personal health data." (Filing No. 89 at p. 16). Defendants also argue these requests are unreasonably cumulative or duplicative.

Plaintiffs have agreed to limit the date range for these requests to the period of 2008 through 2016, which covers the date when Defendants first developed the Virtue through two years after it was implanted in Mr. Beller. Plaintiffs contend that these Requests seek the production of all documents and emails, including Defendants' internal communications, regarding any complaints, adverse events, and complications with the Virtue product. Plaintiffs assert that Defendants have only produced a "redacted three-page table of people who have complained about the Virtue product and certain short reports, generated by Defendants, about one or more of these individuals' complaints." Defendants have not produced: emails about these complaints and adverse events; their internal communications about these complaints and adverse events; or all their emails about the complications associated with the Virtue product. (Filing No. 93 at pp. 28-30).

Court Ruling: Although these document requests will likely entail a substantial search and production of documents, Plaintiffs have shown that the documents sought in these requests may be relevant to their claims. In particular, Plaintiffs' requests are directed at obtaining information about whether Defendant knew or had reason to know that the product was, or likely to be, dangerous when put to the use for which it was manufactured. However, as stated above, the relevant time period for such inquire is February 2008 through January 24, 2014. Defendants shall supplement their production accordingly after the parties' ESI conference.

REQUEST NO. 27: Plaintiffs agreed to narrow this Request to only seek the production of "any published or unpublished medical or scientific articles and research papers regarding any complications or health effects of all versions of the Virtue Device." (Filing No. 84 at p. 34.) Defendants represent that they have produced these documents. (Filing No. 89 at p. 9). Accordingly, the motion to compel as to this request is denied.

> **REQUEST NO. 29**: All Documents in Your possession, custody or control related to pre-clinical testing conducted that involves the Virtue Device including but not

> limited to all data concerning animal studies, competitive studies, scientific studies, registries, head-to-head studies, parallel studies, randomized controlled trials, and/or double blind studies.

Defendants assert they produced documents responsive to this request in their response to Request No. 15, which asked for pre-clinical and clinical study reports. Defendants state they produced the testing "that served to qualify Virtue for sale by the FDA . . . as part of the design history file: E.g. "Muscle Implantation Study of Surgical Mesh in the Rabbit (10 and 30 days)" at Bates No. CP_Beller 90028426." (Filing No. 89 at p. 17).

Plaintiffs primarily request supplementation of this request to include all emails related to pre-clinical trials and testing before Defendants placed the Virtue on the market in 2009. Plaintiffs assert those emails are relevant to show "what types of tests Defendants were running, or proposed to run, on the Virtue product before releasing it onto the market – and whether those tests were appropriate to judge the efficacy and/or safety of the Virtue." Plaintiffs assert they "have produced expert testimony that Defendants' clinical studies, tests, and trials were deficient and that Defendants knew or should have known that their product was not indicated for a patient like Mr. Beller." (Filing No. 93 at p. 31).

Court Ruling: Plaintiffs have shown that the documents sought in this request are relevant to their claims, and Defendants have not met their burden to show that responding would be an undue burden or otherwise objectionable. Defendants shall supplement this request after the parties' ESI discovery conference.

> **REQUEST NO. 30**: All Documents in Your possession, custody, or control comprising or regarding Your internal communications pertaining the safety and/or efficacy of the Virtue Device.

Defendants argue that this request is facially overbroad, but during the parties' meet and confer stated they would produce internal communications. Plaintiffs are concerned that Defendants have limited their definition of "Virtue Device" to the version implanted in Mr. Beller, and not all iterations. (Filing No. 84 at p. 36; Filing No. 89 at p. 18).

Court Ruling: Following the parties' ESI conference, Defendants shall produce documents regarding all versions of the Virtue responsive to this request, between February 2009 and January 24, 2014.

REQUEST NO. 32: All internal communications concerning what information should be provided to consumer, physicians or other healthcare professionals concerning the safety risks and/or efficacy of the Virtue Device including, but not limited to, draft and approved informed consent forms.

Defendants argue that this request is unduly burdensome and overbroad, and that Plaintiffs' request for draft and approved informed consent forms is neither relevant or proportional to the needs of the case. Defendants assert that "[t]he complaints are disclosed in the literature, and Plaintiffs have enough information based on the marketing materials and studies to make their arguments about the product's safety and efficacy." (Filing No. 89 at p. 19). Plaintiffs state they "want to see the internal communications that Defendants exchanged about their product that shows their knowledge that they were selling a bad product." (Filing No. 93 at p. 33).

Court Ruling: Plaintiffs claim that "Defendant[s] knew or had reason to know that the product was, or likely to be, dangerous when put to the use for which it was manufactured" and that they "failed to provide an adequate warning of that danger to foreseeable users of the product." (Filing No. 19 at p. 6). Plaintiffs' request seeks information relevant to their claims. Defendants shall supplement their production responsive to this request following the parties' ESI discovery conference.

REQUEST NO. 33: Plaintiffs agreed to narrow this Request "to only seek any agreements and contracts (including any amendments thereto) between any of the Defendants and any third-parties regarding any analysis of the safety or efficacy of any version of the Virtue Device during the period of 2008 through 2016." (Filing No. 84 at pp. 37-38). In response, Defendants stated they "will produce the agreements and contracts." (Filing No. 89 at p. 9). To the extent they have not already done so, Defendants shall produce documents responsive to Plaintiffs' narrowed request.

REQUEST NO. 34: All Documents concerning a comparison of the safety and/or efficacy between the Virtue Device and other treatments and/or products used for stress urinary incontinence.

REQUEST NO. 37: All draft and final package inserts, product labels, and instructions for use provided for any Virtue Device during the Relevant Time Period, including any Documents identified in Section B of the Defendants' Rule 26 Disclosures.

Court Ruling: Defendants did not address or contest Plaintiffs' arguments regarding Request No. 34 and Request No. 37. Accordingly, Defendants shall withdraw their objections to these requests and fully supplement these requests to the extent they have not already done so.

REQUEST NO. 35: Plaintiffs have agreed to narrow this Request to "production of any agreements or contracts between any of the Defendants and anyone else regarding the testing, research, development, and/or evaluation of any version of the Virtue product at any point during the period of 2008 through 2016." (Filing No. 84 at p. 39). Defendants has agreed to produce "consulting agreements related to the Virtue male sling." (Filing No. 89 at p. 9). To the extent Defendants have not done so, they shall produce documents responsive to Plaintiffs' narrowed request set forth above.

> **REQUEST NO. 38**: All instructions for physicians concerning the recommended procedure for implantation and removal of the Virtue Device from patients.

Defendants produced the IFU but did not initially include the "Surgical Protocol" referenced in the IFU. Plaintiffs also clarify that the scope of this request extends to all versions of the Virtue Device, not just the one that was implanted in Mr. Beller. (Filing No. 84 at p, 40-41). Defendants state they have now produced the "Surgical Protocol" without limitation as to the version of the device. (Filing No. 89 at p. 9). However, Plaintiffs maintain that, "by virtue of [Defendants'] objections, Plaintiffs cannot tell whether Defendants have, in fact, produced all instructions for physicians concerning the procedure for implanting and removing the Virtue device. Plaintiffs also cannot tell whether Defendants have produced all versions of any such instructions." (Filing No. 93 at p. 34).

Court Ruling: Defendants shall withdraw objections to this request and serve a supplemental response declaring whether it has produced all instructions for physicians concerning the procedure for implanting and removing the Virtue device. If responsive documents were withheld, Defendants shall produce such those documents.

REQUEST NO. 57: Plaintiffs clarify that they "want Defendants to supplement their response to Request No. 57 by producing the audio and video transcripts for all versions of the Virtue product during the period of 2008 through 2016." (Filing No. 84 at p. 43). Defendants assert that they are not aware of any documents responsive to this request but agreed to

investigate further and will produce responsive documents if they are located. (Filing No. 89 at p. 10). Accordingly, if they have not already done so, Defendants shall serve an amended response (a) identifying Defendants' efforts to obtain and provide responsive documents; (b) indicate whether responsive documents do or do not exist; and (c) indicate whether all responsive documents have been produced after a diligent and good faith effort to locate and identify responsive materials.

In sum, Defendants shall disclose to Plaintiffs the search terms, date ranges, custodians, and custodial locations (e.g., hard drives, networks, servers, etc.) that Defendants used to search for ESI. After the disclosure, the parties are to meet and confer to discuss what, if any, additional search terms, ranges, and custodial locations may be appropriate to perform an additional ESI search (which, unless otherwise agreed, encompasses the time period between February 2008 and January 24, 2014). After the ESI meet and confer, Defendants shall serve supplemental responses to Request Nos. 16, 22-26, 29-30, and 32.

Defendants shall also serve supplemental responses to Request Nos. 2, 17, 21, 31, 33-35, 37-38, and 57 to the extent that they have not already done so.

One or both parties may file a "Statement of Objections to Magistrate Judge's Order" pursuant to NECivR 72.2(a). Such objection will not stay this order pending resolution of such Objection unless a party moves for a stay pursuant to NECivR 72.2(c).

Upon consideration,

IT IS ORDERED:

1. Plaintiffs' Motion to Compel Defendants' Discovery Answers (Filing No. 83) is granted, in part, and in part denied as set forth above.
2. On or before September 4, 2018, Defendants shall serve supplemental answers to Interrogatory Nos. 2, 3, 7, 12, and 13-15, as set forth above;
3. On or before August 27, 2018, Defendants shall disclose to Plaintiffs the search terms, date ranges, custodians, and custodial locations (e.g., hard drives, networks, servers, etc.) that Defendants used to search for ESI.

4. After such disclosure, the parties are to meet and confer to discuss what, if any, additional search terms, ranges, and custodial locations may be appropriate to perform an additional ESI search;
5. If the parties agree on an ESI search protocol, Defendants shall produce supplemental responses to Production Request Nos. 16, 22-26, 29-30, and 32 within twenty-one days of their ESI meet and confer.
6. If the parties cannot agree on a ESI search protocol, they may request the Court's assistance to resolve further disputes.
7. On or before September 10, 2018, Defendants shall serve supplemental responses to Request Nos. 2, 17, 21, 31, 33-35, 37-38, and 57 to the extent that they have not already done so.

Dated this 13th day of August, 2018.

BY THE COURT:

s/ Michael D. Nelson
United States Magistrate Judge